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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,960	11/21/2000	Michael Brines	10165-009-999	6595

20583 7590 07/25/2003

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1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,960

Applicant(s)

BRINES ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Status of Application, Amendments and/or Claims

The amendment filed 26 February 2003 (Paper No. 18) has been entered in full. Claims 7 and 10 were cancelled. The amendment filed 02 May 2003 (Paper No. 19) has been entered in full. Claims 1-6, 8 and 9 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the specification as set forth at page 4 of the previous Office Action (26 August 2002, Paper No. 16) is *withdrawn* in view of the amendment (26 February 2003, Paper No. 8).

The objection to claims 1, 2 and 9 as set forth at page 4 of the previous Office Action (26 August 2002, Paper No. 16) is *withdrawn* in view of the amendment (26 February 2003, Paper No. 8).

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as set forth at page 5 of the previous Office Action (26 August 2002, Paper No. 16) is *withdrawn* in view of the amendment (26 February 2003, Paper No. 8).

Claim Rejections - 35 USC § 112, first paragraph, scope of enablement

Claims 1-6, 8 and 9 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for protection of an excitable tissue comprising administering a non-toxic amount of EPO peripherally to a mammal suffering from a neurodegenerative condition does not reasonably provide enablement for:

a method for the *prevention* or treatment of a *neurodegenerative condition* comprising administering peripherally to a mammal an effective non-toxic amount of EPO for the protection of an excitable tissue.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 3-5 of the previous Office Action (26 August 2002, Paper No. 16).

Applicant states that methods for prevention and treatment are fully enabled by the instant application and submits the Declaration of Michael Brines as evidence (Exhibit F). Applicant asserts that the Brines Declaration presents the results of successful experiments that demonstrate the efficacy of EPO treatment in protection against neurodegenerative conditions in two art-recognized models of human neurodegenerative conditions, the rat experimental neuropathy model and the mouse SOD model. Applicant maintains that the results of experiments carried out with both model systems demonstrate that EPO treatment, administered in accordance with the methods disclosed in the application as originally filed, provides a protective benefit for a number of neuropathological symptoms and conditions found in these animal models.

In addition, Applicant submits that common mechanisms underlie many of these various neurodegenerative disorders. Applicant states that oxidative stress resulting

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from free radical mechanisms causes the neuronal cell death and progression of neuropathology, the primary cause of many such neurodegenerative diseases.

Applicant's arguments have been fully considered but not deemed persuasive.

The specification is not enabled for a method of preventing or stopping neurodegenerative condition comprising administering peripherally to a mammal an effective non-toxic amount of EPO for the protection of an excitable tissue. The subject matter sought to be patented as defined by the claims (prevention and neurodegenerative conditions) is not supported by an enabling disclosure.

Neurodegenerative conditions encompass diseases such as Alzheimer's disease (AD) and Parkinson's disease (PD). Prevent means to completely stop a condition from occurring. "Prevention" is not a relative term, it is total. The art has not established that diseases such as AD and PD can be totally prevented. The experiments executed by Dr. Brines demonstrated a "reduction of the severity of the neurodegenerative symptoms" of diabetes and amyotrophic lateral sclerosis but failed to completely "prevent a neurodegenerative condition" upon peripherally administering EPO. While the diseases cited by Applicant may share the common mechanism of oxidative stress, there are many other elements, which characterize these conditions that are vastly different. The state of the prior art establishes various treatments for neurodegenerative diseases. A very high degree of evidence is required, which is accepted in the art, that an absolute protection from the pathology exists over an extended period of time.

Lastly, a certain amount of neuronal death has already occurred in neurodegenerative conditions. The art has not established therapies that can reverse

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primary neurodegeneration, at best therapies can be administered to treat or limit secondary neurodegeneration. However, it might not be sufficient to attenuate the neurologic symptomatology. Thus, the scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

0196.

RMD
RMD

July 14, 2003

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER